

REMARKS

In the instant Office Action, claims 1-19 are listed as pending and all claims stand rejected. Claim 1 is amended to correct grammatical errors. No claims are canceled and no new claims are added.

1. Claim Rejections – Double Patenting

A) Rejection of claims 1-19 on the ground of nonstatutory obviousness-type double patenting

On pages 2-3 of the instant Action, the Examiner rejects claims 1-19 as being unpatentable over claims 1-5 of U.S. Patent No. 5,763,200. The details of the Examiner's reasoning and rejection is found on pages 2 and 3 of the instant Action and are not reiterated in full in this reply.

B) Request for Terminal Disclaimer.

Without conceding to the correctness of the Examiner, and solely in an effort to advance the prosecution of pending claims 1-19, Applicants submit a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c). Applicants respectfully attest that the alleged conflicting U.S. Patent No. 5,763,200 and the above-captioned application have been at all times commonly owned by Societe de Conseils de Recherches et d'Applications Scientifiques, S.A.S., as required under 37 C.F.R. §1.130(b) and that said disclaimer meets all the requirements of 37 C.F.R. §3.73(b).

C) Request for withdrawal of rejection of claims 1-19 under nonstatutory obviousness-type double patenting

Applicants respectfully submit that this request for a Terminal Disclaimer effectively renders moot the nonstatutory obviousness-type double patenting rejection of claims 1-19 over the claims of U.S. Patent No. 5,763,200. Applicants request the reconsideration and withdrawal the rejection of claims 1-19 under the judicially created doctrine of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,763,200.

2. Claim Rejections – 35 U.S.C. § 103(a)**A) Rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)**

On pages 3-5 of the Instant Action, the Examiner rejects claims 1-3, 5, 7-11, 13, 15, 16 and 18 as being unpatentable in light of Inoue (Horm. Metab. Res., 1992, 24:251-253; referred to hereinafter as Inoue) taken with Moore (Biochem. Biophys. Res. Comm., 1991, 179:1-9; referred to hereinafter as Moore) and Yamada (Birham Biophys. Res. Comm., 1993, 195:844-852; referred to hereinafter as Yamada). The details of the Examiner's reasoning and rejection are found on pages 3-5 of the instant Action and are not reiterated in full in this reply.

B) Claims 1-3, 5, 7-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore and Yamada

The Examiner alleges that it would have been obvious to use the method of Yamada "for determining binding compounds for SSTR-5, followed by evaluation of the biological effects of SSTR-5 compounds using the method of Moore or Inoue to inhibit amylin secretion in pancreatic cells . . .". The Examiner concludes that this combination of references hinges upon Yamada suggesting "use of somatostatin subtypes (e.g. SSTR-5 agonists) should reveal the molecular bases for somatostatin function, which includes exocrine and endocrine function (e.g., amylin inhibition) in the pancreas, pituitary and GI tract."

Applicants respectfully disagree and submit that the method of instant claims 1-3, 5, 7-11, 13, 15, 16 and 18 is not obvious in light of Inoue, Moore and Yamada. Yamada discloses that somatostatin inhibits endocrine and exocrine secretion in the pituitary, pancreas and gastrointestinal tract (p 845 lines 1-2) and that knowledge of the five receptor types should aid in elucidating the mechanism/regulation of somatostatin function and lead to the development of selective analogs for clinical applications. Yamada also discloses a method useful to determine if a given compound binds to a somatostatin receptor. Inoue and Moore disclose methods to determine if a given compound inhibits the release of amylin from pancreatic tissue or pancreas cells.

Applicants submit, however, that the combination of these three references does not teach or suggest all aspects of Applicants claimed method of determining the ability of a compound to both bind an SSTR-5 receptor and inhibit amylin release. As recited in the MPEP at 2143.03, "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)". Applicants submit that the important step of the method of claim 1 teaching "if and only if said compound is determined to be able to bind to somatostatin type-5 receptor" is not taught in this combination of references. Thus Applicants submit that as this combination of references fails to teach or suggest all aspects of Applicants method, the references fail to make obvious the instant method.

Applicants submit that the cited references fail to teach that compounds binding to the SSTR-5 receptor are the preferred compounds as none of Inoue, Moore or Yamada teach the investigation of SSTR-5 ligand/receptor in particular. The cells used by Moore and Inoue express all five of the somatostatin (SST) receptors and Yamada fails to teach the advantage of the SSTR-5 over the remaining four SST receptors or even the SSTR-4 receptor described in the cited reference. The combination of Inoue, Moore and Yamada provide no teaching or suggestion to focus on any single SSTR receptor, let alone an SSTR-5 receptor.

Applicants further submit that the combination of Inoue, Moore and Yamada fails to teach or suggest any link between the SSTR-5 receptor and the release of amylin. Applicants clearly demonstrate the link between a particular SSTR receptor, i.e., SSTR-5, and the inhibition of amylin release (see the specification at page 18 line 31 through page 19 line 10 and Figures 1, 2 and 3).

Thus, it would not have been obvious nor could it have been obvious from the combination of Inoue, Moore and Yamada to develop a method to determine the ability of a compound to both bind an SSTR-5 receptor and, if and only if said compound bound to an SSTR-5 receptor, investigate the ability of said compound to inhibit amylin release. The combination may have led to the attempt to determine if a compound bound any SST receptor or which compound binding any SSTR inhibited amylin release,

but would not have taught the skilled artisan the method of *first determining* the ability of a compound to bind to a somatostatin type-5 receptor, and, *if and only if the compound bound an SSTR-5 receptor*, to go on and determine if that compound inhibited amylin release from amylin-secreting pancreas cells.

C) Request for withdrawal of rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

Applicants submit that, for reasons cited above, claims 1-3, 5, 7-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore and Yamada. Applicants respectfully submit that the rejection of claims 1-3, 5, 7-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a) has been obviated. Applicants respectfully request that said rejection be withdrawn.

3. Claim Rejections – 35 U.S.C. § 103(a)

A) Rejection of claims 1-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

On pages 5-6 of the Instant Action, the Examiner rejects claims 1-11, 13, 15, 16 and 18 as being unpatentable in light of Inoue (Horm. Metab. Res., 1992, 24:251-253; referred to hereinafter as Inoue) and Moore (Biochem. Biophys. Res. Comm., 1991, 179:1-9; referred to hereinafter as Moore) taken with Yamada (Birham Biophys. Res. Comm., 1993, 195:844-852; referred to hereinafter as Yamada) and further taken with Hoyer (Arch. Pharm., 1994, 350:441-453, referred to hereinafter as Hoyer). The details of the Examiner's reasoning and rejection are found on pages 5-6 of the instant Action and are not reiterated in full in this reply.

B) Claims 1-3, 5, 7-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore, Yamada and Hoyer

The Examiner alleges that it would have been obvious to use Hoyer's cell preparations of rat olfactory bulb cells expressing SSTR-5 or CHO-K1/SSTR-5 cells or Hoyer's somatostatin agonists with the method of Yamada combined with the methods of Moore or Inoue to first determine the ability of a compound to bind to a somatostatin type-5 receptor, and, *if and only if the compound bound an SSTR-5 receptor*, to go on and

determine if that compound inhibited amylin release from amylin-secreting pancreas cells.

Applicants respectfully disagree and submit that the method of instant claims 1-11, 13, 15, 16 and 18 is not obvious in light of Inoue, Moore and Yamada in further view of Hoyer. As discussed above, Applicants submit that Inoue, Moore and Yamada fail to teach or suggest a method of determining the ability of a compound to bind to a somatostatin type-5 receptor, and, *if and only if the compound bound an SSTR-5 receptor*, to go on and determine if that compound inhibited amylin release from amylin-secreting pancreas cells. Applicants submit that Hoyer fails to teach or suggest a link between a compound binding to SSTR-5 and the inhibition of amylin release, and thus cannot overcome the failings in the teachings of Inoue, Moore and Hoyer.

E) Request for withdrawal of rejection of claims 1-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a)

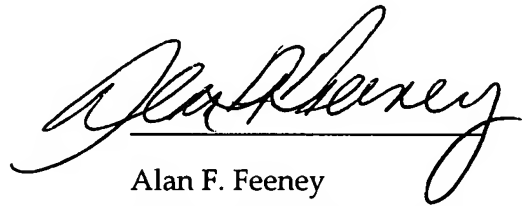
Applicants submit that, for reasons cited above, claims 1-11, 13, 15, 16 and 18 are not obvious in light of Inoue, Moore and Yamada in view of Hoyer. Applicants respectfully submit that the rejection of claims 1-11, 13, 15, 16 and 18 under 35 U.S.C. § 103(a) has been obviated. Applicants respectfully request that said rejection be withdrawn.

Reconsideration of the instant Office Action, entry of the amendments submitted herewith, and allowance of all pending claims are respectfully requested. Prompt and favorable action is solicited.

Respectfully submitted,

Date:

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A handwritten signature in black ink, appearing to read "Alan F. Feeney", written over a horizontal line.

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